

**FOOD AND DRUG ADMINISTRATION (FDA)**  
*Pulmonary-Allergy Drugs Advisory Committee (PADAC)*  
Washington DC/Silver Spring Hilton  
8727 Colesville Road, Silver Spring, Maryland

November 19, 2009

**DRAFT AGENDA**

The committee will discuss new drug application (NDA) No. 21-395, S029, SPIRIVA HANDIHALER, tiotropium bromide by Boehringer Ingelheim, for the proposed indication of prevention of exacerbations in patients with COPD in addition to potential safety signals of stroke, cardiovascular events, and mortality.

8:00 a.m.	Call to Order Introduction of Committee	Mark Brantly, M.D. Acting Chair, PADAC
	Conflict of Interest Statement	Kristine Khuc, Pharm.D., Designated Federal Official, PADAC
8:15 a.m.	Opening Remarks	Badrul Chowdhury, M.D., Ph.D. Director, Division of Pulmonary and Allergy Products Center for Drug Evaluation and Research (CDER)
8:30 a.m.	<b>Sponsor Presentation</b>	<b>Boehringer Ingelheim</b>
9:45 a.m.	Questions to Sponsor for Clarification	
10:00 a.m.	Break	
10:15 a.m.	<b>FDA Presentation</b>	
11:45 p.m.	Questions to FDA for Clarification	
12:00 p.m.	Lunch	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Charge to Committee Discussion of Questions/Vote	
5:00 p.m.	Adjournment	